

## REMARKS

### *1. Status of claims*

After entry of the above amendment, claims 1, 8-10, 32-33, 35-37, 44, and 48 are pending.

### *2. Support for amendment*

The above amendment finds support in the specification at at least p. 7, lines 23-24; p. 8, lines 1-2; and p. 13, lines 9-10. No new matter has been added by this amendment.

### *3. Claim rejections under 35 U.S.C. §112*

The Examiner rejected claims 1-3, 24, and 28 under 35 U.S.C. §112, first paragraph, for allegedly containing new matter. In the above amendment, the phrase ‘wherein said composition has a pH less than 5’ has been removed from the claims. Applicants respectfully submit the basis for this rejection has been removed.

### *4. Claim rejections under 35 U.S.C. § 103*

The Examiner maintained her rejections of claims 1, 3-5, 8, 10, 24-27, and 32-48 under 35 U.S.C. § 103(a) as being unpatentable over Ohura *et al.*, *J. Biomed. Mat. Res.* (1999), 44(2), 168-175 (“Ohura”) in view of Chen *et al.*, US 5,707,962 (“Chen”); and of claims 1-8, 10, and 28-29 under 35 U.S.C. § 103(a) as being unpatentable over Kwan *et al.*, US 6,187,047 (“Kwan”) in view of Constantz, US 5,047,031 (“Constantz”). In light of the above amendment, Applicants respectfully traverse these rejections.

Ohura teaches a bone cement containing  $\beta$ -tricalcium phosphate, monocalcium phosphate monohydrate, and bone growth protein (specifically, recombinant human BMP-2) (Abstract). Chen teaches a composition containing collagen, bone growth protein, and an inorganic filler or particles (col. 2, line 60-col. 3, line 34). The references, alone or in combination, do not teach or suggest a composition as presently claimed. The calcium phosphate materials taught by Ohura and Chen do not guide the skilled artisan to consider calcium hydrogen phosphate dihydrate as the sole calcium phosphate component of a composition as presently claimed. This is especially the case given the unpredictably above-average explant mass, histology score, and mineral mass for calcium hydrogen phosphate dihydrate as shown in Figures 2-3 and 5. Therefore, the combination of Ohura and Chen does not render obvious the claimed invention as a whole, and Applicants respectfully request this rejection as it applies to claims 1, 8-10, 32-33, 35-37, 44, and 48 be withdrawn.

Kwan teaches compositions containing collagen mineralized by reaction with calcium chloride and tribasic sodium phosphate, but Kwan does not identify products of the reaction other than hydroxyapatite, carbonated hydroxyapatite, and fluoridated apatite (col. 2, line 49 to col. 3, line 48). Constantz teaches compositions containing the products of a reaction of a phosphoric acid source, an alkaline earth metal source, and other materials (col. 2, lines 60-68). Constantz gives examples of compositions containing brushite, monetite, and octacalcium phosphate (Example 1) and calcite and hydroxyapatite (Example 2). Neither Constantz nor Kwan teaches a composition containing calcium hydrogen phosphate dihydrate as the sole calcium phosphate component, in contrast to the present claims. The calcium phosphate materials taught by Constantz and Kwan do not guide the skilled artisan to consider calcium hydrogen phosphate dihydrate as the sole calcium phosphate component of a composition as

presently claimed. This is especially the case given the unpredictably above-average explant mass, histology score, and mineral mass for calcium hydrogen phosphate dihydrate as shown in Figures 2-3 and 5. Therefore, the combination of Constantz and Kwan does not render obvious the claimed invention as a whole, and Applicants respectfully request this rejection as it applies to claims 1 and 8-10 be withdrawn.

5. *Conclusion*

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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